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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,694	06/15/2001	Jon Duvick	35718/208255 (5718-111C)	1574
826	7590	01/30/2004	EXAMINER	
ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000			IBRAHIM, MEDINA AHMED	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/882,694

Applicant(s)

DUVICK ET AL.

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' response filed 08/14/03 and the supplemental response of 10/27/03 in reply to the Office action mailed 07/27/03 have been entered. Claims 1-33 are pending and are under examination.

This Office action contains NEW GROUNDS OF REJECTIONS not necessitated by Applicant's amendments. Therefore, this action is non-final. The delay in applying these grounds of rejection is regretted.

All rejections and objections not stated below have been withdrawn.

Claim Objections

In claim 19, part (c), "SEQ ID NO: 3, 5, 8, or 10" should be replaced with ---SEQ ID NO: 3, 5, 8, or 11----.

Claim Rejections - 35 USC § 112

Claims 1-4, 8, 19-22 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 19 are indefinite because the preamble lacks correlation with the last method step. The claim is drawn to a method for reducing pathogenicity to a plant, and the last method step is integrating into the genome of a plant cell.

In claim 20, "said plant cell" in parts (a), (b), and (c) lacks antecedent basis.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of reducing pathogenicity of a fumonisin producing fungus to a plant and plant cell by stably integrating into the genome of said plant and plant cell with specified nucleotide sequences encoding polypeptides having fumonisin detoxification activity, including esterase and amine oxidase activities. The claims are also drawn to plants and plant cells comprising said nucleic acid sequences.

Applicant teaches isolated nucleotide sequences encoding carboxyl esterase, amine oxidase, flavin monooxygenase, aldehyde dehydrogenase, and permease enzymes from *Exophiala spinifera*, *Rhinoctadiella atrovirens*, and the bacterium of ATCC 55552, and prophetic methods of transforming plants with said nucleic acid sequences. Applicant only teaches expression of said nucleotide sequences in E.coli cells to show AP1 degrading activity (Examples 1-8). Applicant does not teach expression of said enzymes in a plant.

Applicant has not provided guidance for a method of reducing toxicity of a fumonisin producing fungi to a plant with the disclosed nucleotide sequences, and it is unclear whether expressing microbial carboxyl esterase, amine oxidase, flavin monooxygenase, aldehyde dehydrogenase, p-glycoprotein or permease in a plant

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would actually led to fumonisin resistant plants for the following reasons: firstly, the reaction catalyzed by microbial esterase or amine oxidase may be reversible, and might have therefore failed to protect plant cells from the fumonisin and/or AP1. Secondly, it is uncertain how the metabolism of the reaction products (for example, 2-OP and ammonia) might affect the plant, e.g. whether introduction of the carboxyl esterase or amine oxidase and/or flavin monooxygenase, aldehyde dehydrogenase, p-glycoprotein or permease would alter plant growth and development in ways that would negate any positive contribution of the enzymes by for example, interfering with the plant's natural disease resistance mechanisms. It is also uncertain, even if fumonisin produced by an invading fungus was efficiently converted to a non-toxin form, whether this conversion would impart reduced fumonisin toxicity upon the plant. Given these uncertainties, it is far from obvious whether expressing the disclosed sequences in a plant would actually led fumonisin tolerant plants.

Furthermore, Applicant has provided no evidence showing that the expression of any microbial enzyme in a transgenic plant would provide the desired phenotype. Therefore, given the lack of guidance, the limited working examples, and the uncertainties relating to microbial carboxyl esterase, amine oxidase, flavin monooxygenase, aldehyde dehydrogenase, and p-glycoprotein or permease activities in a transgenic plant; the claimed method of reducing pathogenicity to a plant/plant cell of a fumonisin producing fungus is not enabled. In addition, one skilled in the art would not know how to use transgenic plant and plant cells stably transformed with said nucleotide sequences.

Written Description

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention does not meet the current written description requirements because SEQ ID NO: 16 and SEQ ID NO:18 are partial DNAs encoding partial proteins. The claims encompass any full-length genes, fusion constructs and cDNAs comprising SEQ ID NO: 16 or 18. The disclosed structural feature does not necessarily constitute a substantial portion of the claims genus. Since Applicant has not described a representative number of nucleotide sequences comprising SEQ ID NO:16 or 18, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that one skilled in the art would recognize that Applicants are in possession of the invention as broadly claimed. In addition, since Applicants has not described the nucleotide sequences as discussed above, methods that employ said nucleotide sequences, and plant/plant cell comprising said nucleotide sequences are similarly not described.

See Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices). See, also *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997) where it states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the

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scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.

Remarks

Claims 1-33 are free of the prior art because the prior art does not teach or suggest the specifically claimed nucleic acid sequences and transgenic plant and plant cells, nor that the prior art teaches a method that employs said nucleic acid sequences.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and After final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

1/19/04
Mai

Medina A. Ibrahim